REMARKS

The present claims, in general, include a protein kinase (PK) domain having a sequence that is at least 90% identical to SEQ ID NO:2.

Claims 1-7, 24-26, 36-46, and 49-50 were examined in this case. Claims 1-7, 24-26, 36-39, 41-46 stand rejected under 35 U.S.C. § 112 first paragraph as lacking a written description. Claims 1-7, 24-26, 36-46, and 49-50 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. And claims 36-46 stand rejected under 35 U.S.C. § 102(b). The present reply amends claim 1, 24, and 36. Each of the Office's rejections is addressed below. Applicant respectfully requests reconsideration of the claims as amended.

Support for the Amendments

Applicants have amended independent claims 1, 24, and 36 to require "a sequence that is at least 90% identical to SEQ ID NO:2". Support for this claim amendment can be found throughout the specification, for example, at page 6, line 9-17, Figure 5, and at page 23, lines 2-4. Claims 24 and 36 have also been amended to require "a fragment of a calcium-dependent protein kinase (CDPK) polypeptide that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2". Support for this amendment is found, for example, at page 27, lines 24-25. No new matter has been added by any of these amendments, and Applicant notes, for the record, that the current claim

amendments were made solely for the purpose of expediting prosecution. Applicant reserves the right to pursue all canceled subject matter in this or future related applications.

Written Description

Claims 1-7, 24-26, 36-46, and 49-50 were rejected under 35 U.S.C. § 112, first paragraph, for lack of a written description. In view of the present amendment, this rejection should be withdrawn.

In order to fulfill the written description requirement of § 112, the patent specification does not need to describe exactly all the subject matter that is claimed. *In re Daniels*, 114 F.3d 1452, 46 U.S.P.Q.2d 1788 (Fed. Cir. 1998); *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 U.S.P.Q. 117 (Fed. Cir. 1985). Rather, the specification must clearly allow a person of ordinary skill in the art to recognize that the inventor has invented what is claimed. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998). In applying this standard, the Federal Circuit has held that the specification must convey with reasonable clarity to a skilled artisan that the inventor "was in possession of the invention" at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).

The Office has asserted that the specification only describes the use of two highly homologous CDPK sequences, obtained from one plant species, that activate a stress

response pathway and thus does not provide an adequate written description for any other CDPK that include a protein kinase domain. Applicant, for the record, notes that, under *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1159, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), "every species in a genus need not be described in order that a genus meets the written description requirement." 43 U.S.P.Q.2d at 1405 (citing *Utter v. Hiraga*, 845 F.2d 993, 6 U.S.P.Q2d 1709 (Fed. Cir. 1988) ("A specification may, within the meaning of § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses."). Nonetheless, in order to advance prosecution, independent claims 1, 24, and 36 now require a calcium-dependent protein kinase (CDPK) polypeptide that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2, wherein the polypeptide increases the level of tolerance, in a plant expressing said polypeptide, to an environmental stress. As stated in the Written Description Guidelines (66 FR 1106),

> [f]actors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

The claimed methods and compositions include DNA molecules that encode proteins that are distinguished from other proteins by both the structural characteristic of

having at least 90% sequence identity to SEQ ID NO:2 and by the specific functional characteristic of increasing tolerance to an environmental stress in a plant.

As clear distinguishing characteristics that are shared by the DNA molecules recited in applicant's claims are disclosed in applicant's specification and because the claims, as amended, are in accordance with the PTO's applicable standard for determining compliance with the written description requirement, this rejection should be withdrawn.

Scope of Enablement

Claims 1-7, 24-26, 36-46, and 49-50 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Office asserts that the specification does not reasonably provide enablement for claims drawn to producing transgenic plants that are tolerant to any environmental stress other than drought, or for claims directed to producing transgenic plants that are tolerant to environmental stresses as a result of the overexpression of transgenes encoding any CDPK polypeptide other than a transgene encoding a PK domain of AtCDPK1. Applicants respectfully traverse this rejection.

As an initial matter, applicant again notes that the claims now require a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2, a domain which is acknowledged by the Office to effect stress tolerance. The scope of these claims is therefore limited to sequences that are highly homologous, and therefore necessarily structurally similar, to the disclosed sequence. Moreover, with the recitation

of a specific level of identity in the claims to the PK domain of a CDPK shown to promote stress tolerance, no undue trial and error experimentation would be required to identify and distinguish CDPKs that increase the level of tolerance of a plant to an environmental stress from those CDPKs that do not provide such tolerance.

Turning to environmental stresses other than drought, the Office asserts "one wishing to practice the invention would have to proceed by trial and error experimentation, testing each particular CDPK polypeptide for its ability to protect a palnt against one or more environmental stresses." In essence, the Office reasons that a large amount of screening would be required in order to determine which CDPK polypeptides effectively increased a plant's tolerance to a particular environmental stress other than drought. However, even if this assertion were accurate, the mere fact that one skilled in the art would be required to screen a large number of different embodiments does not mean that undue experimentation is required to practice the invention. In *Ex parte Chen*, 61 U.S.P.Q.2d 1025 (Bd. Pat. App. & Int. 2000), only 1% of the 1746 attempts at integrating a transgene into embryos were successful. Despite this apparently low success rate, the Board held that the claims were enabled. According to the Board, these numbers merely reflected "the need for a repetitive procedure, rather than undue experimentation by those wishing to practice the invention." *Id.* at 1028. The Board's decision in *Chen* is consistent with prior Federal Circuit precedent, which has clearly established that experimentation is not "undue" simply because an extensive amount is

required. See also MPEP (§ 2164.06) citing *In re Wands*, (858 F.2d 731, 8 USPQ2d 1400 (Fed Cir. 1988)) ("The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." (emphasis added.))

The instant specification, on page 36, under the heading "Engineering Stress-Protected Transgenic Plants," provides a detailed description of techniques as to how to obtain plants having tolerance to a variety of environmental stresses. In particular, a working example of the expression of a PK domain gene in tomato to increase the salt stress tolerance is presented. Based on this description in the specification, for example, a skilled artisan, using no more than routine experimentation, could easily screen salt-tolerant plants expressing a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2. Such screening could easily be accomplished using standard techniques for generating transgenic plants and thus does not constitute undue experimentation. All that is required is routine, repetitive experimentation; nothing more. Thus, the present situation is, in all important aspects, indistinguishable from the operative facts in *Chen,* in which the Board held that the applicant's claims directed to transgenic organisms were enabled, despite the necessity for additional experimentation, because the methodology involved a repetitive procedure that was straightforward. Like the situation in *Chen*, applicant's specification explicitly describes the methodology used to arrive at the

claimed invention that includes producing plants having tolerance to environmental stresses other than drought. It, therefore, follows that the present claims are also enabled, even if some routine screening would be necessary to identify a plant that is tolerant to an environmental stress other than drought.

For the above reasons, applicant respectfully requests that the rejection under U.S.C. § 112, first paragraph, for lack of enablement be withdrawn.

Anticipation

Claims 36-46 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Urao et al. (Mol. Gen. Genet. 244:331-340, 1994). The Office maintains that the disclosure of full-length CDPK polypeptides by Urao discloses a DNA molecule encoding a PK domain consisting essentially of itself.

Applicant has overcome this rejection by amending claims 24 and 36 to require a fragment of a calcium-dependent protein kinase (CDPK) polypeptide. In view of this amendment and because Urao fails to disclose a CDPK fragment, applicant respectfully submits that the rejection be withdrawn.

CONCLUSIONS

Applicant submits that the claims are now in condition for allowance, and such action is respectively requested.

Enclosed is a Petition to extend the period for replying to the Office Action for three months, to and including April 6, 2004, and a check for $475.00 in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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